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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,445	11/13/2001	A. Neil Barclay	DX 01052K1	1467

28008 7590 06/30/2005

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,445	BARCLAY ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9-23 is/are rejected.

7)☒ Claim(s) 22 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-23 are pending in the application.

This Office Action is in response to the Amendment filed on 6/8/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/8/05 has been entered.

Response to Amendment

Acknowledgement is made of Applicant's submission of sequence listing which corrects the previous mistake. The listing is accepted and entered.

The rejection of claims 9-12, 15-23 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 9-23 under 35 U.S.C.101 is maintained for reasons set forth of the record mailed on 2/17/05 and further discussed below.

The rejection of claims 9-23 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 2/17/05 and further discussed below.

The rejection of claims 13 and 14 under 35 U.S.C. 112 2nd paragraph is maintained for reasons set forth of the record mailed on 2/17/05.

Claim 22 is objected for reasons set forth of the record mailed on 2/17/05.

Response to Arguments

Claim Rejections - 35 USC § 101

Claims 9-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility.

In response to this rejection, Applicants argue that the disclosed utility is substantial, specific and credible because the specification discloses a number of specific utilities for CD200R including functioning in inflammatory conditions, multiple sclerosis, rheumatoid arthritis, and autoimmune disease. Applicants assert that the antibody to CD200R would have utility as a therapeutic or diagnostic agent. Applicants further assert that CD200 is a cell surface protein identified on a number of cells including lymphocytes, endothelial cells, and dendritic cells, which are known to contribute to inflammatory conditions, multiple sclerosis, rheumatoid arthritis, and autoimmune disease. Applicants thus conclude that the diseases listed are not unspecific. Furthermore, Applicants assert that the disclosed utility is substantial because an antibody specific for CD200R that can potentially treat or diagnose the above diseases. Applicants further assert that the previously cited references demonstrate the role of CD200R *in vitro* and in animal models recognized by skilled artisan as predictive of human disease. Specifically, Applicants argue that Hoek et al. teach the specific relationship between CD200R and multiple sclerosis and rheumatoid arthritis because CD200 mediates its effects through CD200R interaction, wherein the models used by Hoek et al. and Gorczynki et al. are well accepted model for those disease in the art. Moreover, Applicants argue that Foster-Cuevas demonstrates that human CD200R functions down-regulate macrophages, thus eliciting

immunosuppression, and the specification teaches this utility as well. Applicants further provide Cherwinski et al. to demonstrate the inhibitory effect of an antibody against human CD200R in a leukocyte population. Applicants thus conclude that the claimed invention has credible, substantial and specific utility.

The above arguments have been fully considered but deemed unpersuasvie. The claims are rejected for same reasons as discussed in the previous office action. In response to Applicant's argument with regard to substantial, specific and credible uses, the examiner maintains the position that the specifiction fails to teach a substantial, specific and credible use for the binding compound. Although CD200 is known as a cell surface antigen identified in some specific cell type that are involved in inflammatory conditions, multiple sclerosis, rheumatoid arthritis, and autoimmune disease, the specification does not teach which specific disease is the result from the this particular CD200R. In other words, the specification does not teach which specific pathway in any specific cell type that leads to a specific disease. The list provided in the specification is based on the involvment of cells, for example, macrophages and dendritic cells, which are known to be involved in such diseases. However, there is no teaching whether the involvement of such cells in those diseases is result from the expression of said CD200 antigen. Applicants are reminded that expression of a protein in certain cell type does not mean that said protien is responsible for all the activity of such cell type. Thus, the disclosure provided in the specification is a laundry list of the disease that are associated with the cells expressing said antigen, which does not provide a specific association between said diseases and CD200R. Therefore, the specification fails to teach a specific, substantial and credible

function to the CD200R. As such, the antibody to said receptor does not have specific, substantial and credible utility as well.

With regard to the cited art, all of them are post filing (which includes Cherwinski et al). As discussed previously, the teaching of the post filing art is not taught in the appliation, wherein the statue requires that the utility of the claimed invention is known at the time of filing. Moreover, none of reference establishes a direct relationship between the CD200R and the diseases that are alleged to result from the receptor dysfunction. With regard to Hoek et al., contrary to Applicant's assertion, this reference does not teach the relationship between the disease and the lack of the exprssion of CD200 is mediated through this specific CD200R. It is well known in the art many peptides may exert different effects through different pathways which is mediated through different receptors. There is no evidence suggest that this CD200R is the only receptor which is responsible for the effect observed in the knockout mouse model as disclosed in Hoek et al. Whether the animal model disclosed in Gorczynki and Hoek et al. is accepted in the art has no relevance to demonstration of a direct relationship between CD200R and rhumatoid arthritis and multiple sclerosis.

With regard to Foster-Cuvas, contrary to Applicant's assertion, the specification does not disclose the same teaching. The paragraph cited by Applicants is an example from the laundry list. Such teaching is not sufficient to support a credibe, substantail and specific utility for CD200R encoded by SEQ ID NO:20. Similarly, the teaching provided in Cherwinski et al. (published on 9/25/03) is not taught in the specificaiton either. As such, Applicants fail to teach a credible, substantial and specific use for the claimed invention. Therefore, this rejeciton is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the specification provides adequate written description for the claimed CD200R-binding compounds because the specification discloses the isolation of the novel CD200R antigen and provides its amino acid sequence and nucleic acid sequences. The specification discloses antibodies specific to CD200R and methods of making said antibodies. Applicants argue that the level of skill and knowledge in the art of antibodies at the time of filing is high, and the production of antibodies against a well-characterized antigen was conventional. Applicants thus conclude that the written description requirement is satisfied.

The above argument has been fully considered but deemed unpersuasive. The claims are rejected for same reasons as discussed in the previous office action. In response to Applicant's argument, Applicants are reminded not to confuse the written description requirement with the enablement requirement, in which it requires the specificaiton has to describe the structure and relevent characteristics of the claimed genus, which is not equivalent to the description of

method for how to make the claimed invention. Applicants are also remined that the claims are not limited to antibodies to SEQ ID NO:20, it encompasses binding compounds comprising an antigen binding site from an antibody, wherein said antibody binds to a polypeptide comprising mature SEQ ID NO:20 or a fragment. In other words, the claimed binding compounds would include those comprising binding sites from an antibody which bind to a polypeptide comprises SEQ ID NO:20 and fragments. Such antibody may not even binds to SEQ ID NO:20 itself. In view of the genus of the claimed invention, the specification fails to describe a representative number of species by their complete structure and other identifying characteristics. Therefore, the written description requirement is not met, and this rejeciton is maintained.

Claims 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants argue that the specification is sufficiently enabling to allow one skilled in the art to synthesize without undue experimentation the claimed invention. Applicants argue that the specification teaches the sequences of the antigen and the making the antibody with known sequence is well known in the art. Applicants thus conclude that the claimed invention is enabled.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement of the claimed invention is set forth in the previous office action. In response to Applicant's argument, Applicants are again reminded that 1) the claimed scope is not

limited to antibody; 2) the statue also requires the specification to teach how to use the claimed invention. Although one skilled in the art would be able to make antibodies to SEQ ID NO:20 and fragments within, whether the skilled artisan can make binding compounds other than the antibodies, or antibodies of fragments of the polypeptide which is not encompassed by SEQ ID NO:30 (note: the claim recites "a polypeptide comprising mature SEQ ID NO:20) is unpredictable. Moreover, whether the skilled artisan can use the claimed binding compound according to the embodiments of the specification is also unpredictable. As such, the specification fails to provide enablement for how to make binding compound that are not antibody and how to use the claimed inventions. Therefore, this rejeciton is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants did not respond to this rejection. Therefore, this rejection is maintained for same reasons as set forth in the office action mailed on 2/17/05.

Claim Objections

Claim 22 objected to because of the following informalities: claim 22 recites "some fragment". Applicants are reminded to amend the fragment into plural form. Appropriate correction is required.

Applicants have not respond to the objection, thus it is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner
Art Unit 1636
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PATENT EXAMINER